REMARKS

The Office Action mailed July 25, 2008, has been received and reviewed. Each of claims 1-12 and 14-27 stands rejected. Claims 1, 10, and 19 have been amended herein and claims 6, 8, and 18 have been canceled. Accordingly, claims 1-5, 7, 9-12, 14-17, and 19-27 remain pending. Care has been exercised to introduce no new subject matter. Reconsideration of the above-identified application in view of the above amendments and the following remarks is respectfully requested.

Rejections based on 35 U.S.C. § 102

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdeggal Brothers v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 2 USPQ 2d 1913, 1920 (Fed. Cir. 1989). *See also*, MPEP § 2131.

Claims 1-12 and 14-27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Publication Number 2002/0188469 to Shalmi et al. (hereinafter the "Shalmi reference"). The cancellation of claims 6, 8, and 18 renders moot the rejection of those claims. As the Shalmi reference fails to describe, either expressly or inherently, each and every element of claims 1-5, 7, 9-12, 14-17, and 19-27, Applicants respectfully traverse the rejection, as hereinafter set forth.

Claim 1, as presently amended, recites a system for managing clinically related supply procurement according to outcomes. The system includes a first interface to receive patient supply data captured from at least one clinically related site, the patient supply data comprising clinical supplies, including a first clinical supply and a second clinical supply, used

to treat one or more patients. The system also includes a second interface to receive clinical outcomes data from the at least one clinically related site. The clinical outcomes data describes one or more patient outcomes for the one or more patients that resulted from using the clinical supplies, including a first clinical supply and a second clinical supply, to treat the one or more patients. A patient outcome is a comparison of a present patient condition relative to an initial patient condition at the time a clinical supply was used to treat a patient. The system further includes an analytic engine, the analytic engine communicating with the first interface and the second interface to generate comparative clinical supply reports showing a comparison of the one or more patient outcomes for the one or more patients that resulted from the use of a first clinical supply with the one or more patient outcomes that resulted from the use of a second clinical supply. Support for "a patient outcome is a comparison of a present patient condition relative to an initial patient condition at the time a clinical supply was used to treat a patient" is found in paragraph [0047] of the present specification. Support for comparing results of the first clinical supply and the second clinical supply is found in paragraph [0036] of the present specification and in "alternative supply selections" as recited in originally filed claim 5.

The Shalmi reference, on the other hand, describes a pharmaceutical distribution and sales system by which a drug manufacturer contracts with a customer (e.g. a hospital) to supply certain quantities of the drug based on potential patient use. The purpose of the system is to minimize financial risk for customers purchasing the costly drugs, while at the same time ensuring an adequate supply of drugs for patients. *See* Shalmi reference Abstract. The Shalmi reference describes tracking customer inventory to make sure adequate supplies of drugs are available. *See* Shalmi reference [0053].

Applicants respectfully assert that the Shalmi reference fails to describe, either expressly or inherently, an "interface to receive clinical outcomes data from the at least one clinically related site that describes one or more patient outcomes for the one or more patients that resulted from using the clinical supplies, wherein a patient outcome is expressed by comparing a present patient condition relative to an initial patient condition." Thus, the clinical outcomes data describes the outcome or result of a patient's treatment with a clinical supply. The outcome is the comparison of the patient's current condition with the patient's initial condition at the time of treatment with the clinical supply. In contrast, the Shalmi reference describes tracking a customer's use of a drug provided by a manufacturer. The Shalmi reference describes receiving a customer order when the supply of a drug falls below a limit, or directly tracking a customer's drug inventory. *Id.* The drug inventory information does not describe the outcome or result of treatment with a drug. Thus, the Shalmi reference does not describe an "interface to receive clinical outcomes data that describes one or more patient outcomes that resulted from using the clinical supplies."

Further, Applicants respectfully assert that the Shalmi reference does not describe an "an analytic engine . . . to generate comparative clinical supply reports showing a comparison of the one or more patient outcomes for the one or more patients that resulted from the use of a first clinical supply with the one or more patient outcomes that resulted from the use of a second clinical supply." The analytic engine in claim 1 generates a report that compares the effectiveness of two different clinical supplies by comparing patient outcomes (i.e., present condition vs. initial condition at time of treatment) for one or more patients that were treated with a first clinical supply vs. a second clinical supply. The comparison helps users decide which clinical supply to use in the future. In contrast, the Shalmi reference describes analyzing

historical usage data to anticipate future usage data. The anticipated usage data forms the basis of a supply agreement between a customer and manufacturer. *Id.* at [0056]. The analysis in the Shalmi reference does not compare the effectiveness of one drug with effectiveness of another drug in treating a condition in patients. Thus, an "an analytic engine . . . to generate comparative clinical supply reports . . . " is not described by the Shalmi reference.

As the Shalmi reference fails to describe, either expressly or inherently, every element of independent claim 1, Applicants respectfully submit that claim 1 is not anticipated by the Shalmi reference. Each of claims 2-5, 7, and 9 depends, either directly or indirectly, from independent claim 1 and define further patentable features. For example, claim 4 recites a system according to claim 1, wherein the clinical outcomes data comprises at least one of patient mortality data, patient morbidity data, patient ambulatory data, patient infection data, patient prescription data, patient length of stay data, patient condition data, and patient readmittance data. It is stated in the Office Action of July 25, 2008, that "patient prescription data" is described in paragraph [0053] of the Shalmi reference. *See* Office Action p. 3. Applicants submit that "patient prescription data" in not described in the cited section, or any other part, of the Shalmi reference. To the contrary, this section of the Shalmi reference describes tracking the amount of a hemostatic agent used to treat patients. *See* Shalmi reference [0053]. This is unrelated to patient prescription data that provides information about a patient outcome. It is also stated that claim 4 is simply a list of data that is not given patentable weight. *See* Office Action p. 10. Claim 4 is not a list of data, but a list of metrics for measuring clinical outcomes. When read in conjunction with claim 1, claim 4 does not simply recite a list of data in a database. Accordingly, the Shalmi reference does not anticipate claim 4.

Accordingly, it is respectfully submitted that claims 2-5, 7, and 9 are not anticipated by the Shalmi reference for at least the above-cited reasons. As such, withdrawal of the 35 U.S.C. § 102(b) rejection of claims 1-5, 7, and 9 is respectfully requested.

As presently amended, claim 10 recites a method for managing clinically related supply procurement according to outcomes. The method includes receiving patient supply data captured from at least one clinically related site, the patient supply data comprising clinical supplies used to treat one or more patients. The method also includes receiving clinical outcomes data from the at least one clinically related site that describes one or more patient outcomes that resulted from using the clinical supplies to treat the one or more patients, wherein the clinical outcomes data is patient condition data that includes initial patient condition data and present patient condition data. The method further includes generating comparative clinical supply reports that show alternative supply-selections for a particular clinical procedure type based at least on the clinical outcomes data.

For reasons similar to those given with reference to claim 1, Applicants respectfully assert that the Shalmi reference does not describe "receiving clinical outcomes data from the at least one clinically related site that describes one or more patient outcomes that resulted from using the clinical supplies to treat the one or more patients, wherein the clinical outcomes data is patient condition data that includes initial patient condition data and present patient condition data" as recited in claim 10. Further, claim 10 has been amended to recite "generating comparative clinical supply reports that show alternative supply-selections for a particular clinical procedure type based at least on the clinical outcomes data." In other words, the outcome that results from using the clinical supply in one type of procedure is compared with the outcome that results from using a different clinical supply in the same type of procedure.

This comparison allows the effectiveness of similar clinical supplies to be compared on a per procedure basis. In contrast, the Shalmi reference describes tracking drug usage on the inventory level, but not with reference to the type of procedure in which the clinical supply is used. *Id.* Accordingly, the Shalmi reference does not describe, at least, these two features of claim 10.

As the Shalmi reference fails to describe, either expressly or inherently, each and every element recited in claim 10, it is respectfully submitted that the Shalmi reference does not anticipate independent claim 10. Each of claims 11-12 and 14-17 depends, either directly or indirectly, from independent claim 10. Accordingly, each of these claims is not anticipated by the Shalmi reference for at least the above-cited reasons. As such, withdrawal of the 35 U.S.C. § 102(b) rejection of claims 10-12 and 14-17 is respectfully requested.

As presently amended, claim 19 recites one or more computer-readable media having computer-executable instructions embodied thereon for performing a method for managing clinically related supply procurement according to outcomes. The method includes receiving patient supply data captured from at least one clinically related site, the patient supply data comprising clinical supplies used to treat one or more patients. The method also includes receiving clinical outcomes data that describes one or more patient outcomes that resulted from using the clinical supplies to treat the one or more patients from the at least one clinically related site. A patient outcome is a comparison of a present patient condition relative to an initial patient condition at the time a clinical supply was used to treat a patient. The method also includes generating a comparative clinical supply report based at least on the clinical outcomes data that shows a correlation between at least one clinical supply and the one or more patient outcomes. The method further includes storing the comparative clinical supply report in computer accessible memory.

For reasons similar to those given with reference to claims 1 and 10, the Shalmi reference fails to describe, either expressly or inherently, "receiving clinical outcomes data that describes one or more patient outcomes that resulted from using the clinical supplies to treat the one or more patients from the at least one clinically related site, wherein a patient outcome is a comparison of a present patient condition relative to an initial patient condition at the time a clinical supply was used to treat a patient" or "generating a comparative clinical supply report based at least on the clinical outcomes data that shows a correlation between at least one clinical supply and the one or more patient outcomes." As described previously with reference to claim 1, the Shalmi reference does not describe tracking or utilizing clinical outcomes data at all or generating comparative reports based on the outcomes.

As the Shalmi reference fails to describe, either expressly or inherently, each and every element recited in amended independent claim 19, it is respectfully submitted that the Shalmi reference does not anticipate independent claim 19, as amended herein. Each of claims 20-27 depends, either directly or indirectly, from independent claim 19. Accordingly, each of these claims is not anticipated by the Shalmi reference for at least the above-cited reasons. As such, withdrawal of the 35 U.S.C. § 102(b) rejection of claims 19-27 is respectfully requested.

CONCLUSION

For at least the reasons stated above, claims 1-5, 7, 9-12, 14-17, and 19-27 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or johoward@shb.com (such communication via email is herein expressly granted) – to resolve the same.

It is believed that no fee is due in conjunction with the present amendment. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing Attorney Docket No. CRNI.111422.

Respectfully submitted,

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